



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M3771N

Public Health Service

Food and Drug Administration
Nashville District Office
297 Plus Park Blvd.
Nashville, TN 37217

May 26, 2000

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER-00-NSV-18

Garrett
5/25/00
JBL

FACILITY ID# 165720

Brent Barrow, M.D.
Medical Director
Cleveland Community Hospital
2800 Westside Drive, NW
Cleveland, TN 37312

Dear Dr. Barrow:

Your facility was inspected on May 5, 2000 by a representative of the State of Tennessee, on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

Processor QC records were missing 6 consecutive days out of 6 days of operation in the month of 12/1999. This accounts for 100% of processor QC records missing for processor [REDACTED] darkroom at site Cleveland Community Hospital.

NOTE: this item refers to the first 3 items listed under the Level 1 heading of the post inspection report left with your facility at the close of the inspection.

The interpreting physician did not meet the requirement of being licensed by a State to practice medicine: [REDACTED]

Level 2

Phantom QC records were missing for at least two weeks but less than four weeks for unit 1, [REDACTED], Mammo room.

The interpreting physician did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period): [REDACTED]

**Cleveland Community Hospital
Brent Barrow, M.D.**

Level 2 (cont.)

The interpreting physician did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period: [REDACTED] (3 CME's in 36 months)

The interpreting physician did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]

The interpreting physician did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography: [REDACTED]

These specific deficiencies appear on the Post Inspection Report, which was given to your facility at the close of the inspection. These deficiencies are symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Cleveland Community Hospital
Brent Barrow, M.D.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,



Carl E. Draper
Director
New Orleans District Office

CED/krs

cc: State of Tennessee (Madhavi Reddy)
State of Tennessee (Melissa Wolford, 540 McCallie Avenue, Suite 550, Chattanooga, TN 37402-2013)

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191